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| APPLICATION NO.                      | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/726,305                           | 12/01/2003  | Hiidenori Ono        | 03719/HG            | 3097             |
| 1933                                 | 7590        | 10/13/2004           | EXAMINER            |                  |
| FRISHAUF, HOLTZ, GOODMAN & CHICK, PC |             |                      | FERNSTROM, KURT     |                  |
| 767 THIRD AVENUE                     |             |                      | ART UNIT            | PAPER NUMBER     |
| 25TH FLOOR                           |             |                      |                     |                  |
| NEW YORK, NY 10017-2023              |             |                      | 3714                |                  |

DATE MAILED: 10/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |              |
|------------------------------|-----------------|--------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s) |
|                              | 10/726,305      | ONO ET AL.   |
|                              | Examiner        | Art Unit     |
|                              | Kurt Fernstrom  | 3712         |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 1,2 and 5-18 is/are allowed.
- 6) Claim(s) 3 and 4 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/1/03 & 3/19/04.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims depend from claim 1, which recites a process for producing an artificial bone. However, claims 3 and 4 relate to the intended use of the product after its production. It is not clear how claims 3 and 4 provide further steps to a method of producing an artificial bone model. Also, the term "used" is overly broad, and does not adequately define a method step.

### ***Allowable Subject Matter***

Claims 1, 2 and 5-18 are allowed.

Claims 3 and 4 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest a method having all of the limitations of claim 1. While individual features of the claim, including laser sintering, irradiation, and the use of a powder material including synthetic resins and inorganic material are known, there is no suggestion to combine all of the features of claim 1 as recited. As an

example, while Long and Ben-Bassat disclose an artificial bone material which is created using sintering and irradiation processes, there is no suggestion or motivation to provide tomographic information of a natural bone. Similarly, while Barlow discloses an artificial bone implant which is produced based on tomographic data and using sintering processes, there is no suggestion or motivation to employ an irradiation process or to use a synthetic resin and an inorganic filler in the recited amounts. Because the prior art does not disclose or suggest a method having each and every element of claim 1, the claims are allowable as indicated above.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Barlow, Wahlig, Long, Ben-Bassat, Muschler, Fink, Kenna, Mittelmeier, Miyamoto, Tanaka, Chae, Suh, Hakamatsuka, Takata and McGee disclose various methods of producing artificial bone material.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kurt Fernstrom whose telephone number is (703) 305-0303. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Derris Banks can be reached on (703) 308-1745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KF  
October 8, 2004



**KURT FERNSTROM  
PRIMARY EXAMINER**